

What is claimed is:

1. An immunochromatographic system for measuring glycated albumin in a blood sample comprising:
  - a first test strip that measures glycated albumin and a second test strip that measures total albumin; and
  - a measurement device that reads, calculates and displays the result as the percentage of glycated albumin compared to total albumin in the sample.
2. The immunochromatographic system of claim 1, wherein said first test strip is comprised of microparticles coated with a first antibody to glycated albumin and an immobilization agent covalently bound to the membrane strip.
3. The immunochromatographic system of claim 2, wherein said immobilization agent is a second antibody to glycated albumin or phenyl boronic acid.
4. The immunochromatographic system of claim 2 wherein said first antibody to glycated albumin and said second antibody to glycated albumin are individually monoclonal or polyclonal antibodies.
5. The immunochromatographic system of claim 4 wherein the polyclonal anti-glycated albumin antibody used may be the whole antiserum, the IgG fraction or the purified antibody.
6. The immunochromatographic system of claim 2 wherein said microparticles are selected from the group consisting of colloidal gold particles, latex particles, polystyrene particles, acrylic particles or other solid phase microparticles.
7. The immunochromatographic system of claim 6 wherein the size of said microparticles are from approximately 5 nm to 50 nm in diameter.
8. The immunochromatographic system of claim 1 wherein said second test strip is comprised of microparticles coated with a first antibody to albumin and a second antibody to albumin covalently bound to the membrane strip.
9. The immunochromatographic system of claim 8 wherein said first antibody to albumin and said second antibody to albumin are individually monoclonal or polyclonal antibodies.

10. The immunochromatographic system of claim 9 wherein the polyclonal anti-albumin antibody used may be the whole antiserum, the IgG fraction or the purified antibody.

11. The immunochromatographic system of claim 8 wherein said microparticles are selected from the group consisting of colloidal gold particles, latex particles, polystyrene particles, acrylic particles or other solid phase microparticles.

12. The immunochromatographic system of claim 8 wherein the size of said microparticles are from approximately 5 nm to 50 nm in diameter.

13. The immunochromatographic system of either of claims 6 or 12, wherein the size of said microparticles is to be selected from the group consisting of particle size diameters of 10 nm, 20 nm, 30nm and 40 nm.

14. The immunochromatographic system of either of claims 6 or 12, wherein said microparticles may be colored or tagged with a fluorescent compound.

15. The immunochromatographic system of claim 14 wherein said microparticles are colored.

16. The immunochromatographic system of claim 14 wherein said microparticles are tagged with a fluorescent compound.

17. The immunochromatographic system of claim 1 wherein the first test strip and the second test strip may be arranged in parallel; or opposite to each other; or at an angle to each other.

18. The immunochromatographic system of claim 1 wherein the first test strip and the second test strip are enclosed in a rigid cassette.

19. The immunochromatographic system of claim 1 wherein said measurement device is a reflectance spectrometer comprising:

- a reflectance detector for measuring the glycated albumin test result;
- a reflectance detector for measuring the glycated albumin control band
- a reflectance detector for measuring the total albumin test result;
- a reflectance detector for measuring the total albumin control band;
- an internal computer chip for measurement and calculation;

- a liquid crystal display;
- an external port to transfer data to an external computer and/or printer;
- a battery and/or an external power source; and
- a rigid external case with an aperture for inserting the test cassette.

20. The immunochromatographic system of claim 1 wherein said measurement device is a fluorometer composed comprising:

- a fluorescence detector for measuring the glycated albumin test result;
- a fluorescence detector for measuring the glycated albumin control band;
- a fluorescence detector for measuring the total albumin test result;
- a fluorescence detector for measuring the total albumin control band;
- an internal computer chip for measurement and calculation;
- a liquid crystal display;
- an external port to transfer data to an external computer and/or printer;
- a battery and/or an external power source; and
- a rigid external case with an aperture for inserting the test cassette.

21. The measurement device according to claims 19 and 20 further comprising an internal memory chip capable of storing one or more than one test result.

22. The measurement device according to claim 21 whereby the one or more than one test result can be displayed on said measurement device's liquid crystal display in numerical format or in graphical format.

23. The measurement device according to claim 22 whereby the one or more than one test result can be transferred to an external computer or printer.

24. A method of monitoring glycated albumin using a point-of-care assay comprising:

- depositing a drop of blood into a sample well of an immunochromatography system test cassette;
- transferring said blood into the sample application pad thereby allowing blood plasma to pass into a first conjugate pad of a first test strip;
- binding said blood plasma to anti-glycated albumin antibody-coated microparticles in said first conjugate pad;

allowing blood plasma-bound anti-glycated albumin antibody-coated microparticles to migrate across said first conjugate pad to a fixed band of membrane-bound anti-glycated albumin antibody;

binding said blood plasma-bound anti-glycated albumin antibody-coated microparticles to said membrane bound anti-glycated albumin antibody to form a visible band;

inserting said immunochromatography system test cassette into a measurement device; and

providing numerical results of glycated albumin levels.

25. The method of monitoring glycated albumin using a point-of-care assay according to claim 24 further comprising:

depositing a drop of blood into a sample well of an immunochromatography system cassette;

transferring said blood into the sample application pad thereby allowing blood plasma to pass into a second conjugate pad of a second test strip;

binding said blood plasma to anti-total albumin antibody-coated microparticles in said second first conjugate pad;

allowing blood plasma-bound anti-total albumin antibody-coated microparticles to migrate across said second conjugate pad to a fixed band of membrane-bound anti-total albumin antibody;

binding said blood plasma-bound anti-total albumin antibody-coated microparticles to said membrane bound anti-total albumin antibody to form a visible band;

inserting said immunochromatography system test cassette into a measurement device; and

providing numerical results of total albumin levels.

26. The method of monitoring glycated albumin using a point-of-care assay wherein said glycated albumin levels and said total albumin levels are used to determine percent glycated albumin.